

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

SECTION 1: Identification of the substance/mixture and company/undertaking

1.1 Product Identifier

Product Name Contiplan by Clinell

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Use Wipes for the purpose of preventing incontinence associated dermatitis in individuals suffering from continence issues

1.3 Details of the supplier of the safety data sheet

Supplier
GAMA Healthcare Ltd
The Maylands Building
Maylands Avenue, Hemel Hempstead Industrial Estate
Hemel Hempstead
HP2 7TG
United Kingdom
Tel: +44 (0) 207 993 0030
Email: info@gamahealthcare.com

Authorised Representative Emergo Europe BV
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
Tel: +31 (0) 70 345 8570

1.4 Emergency telephone number

Tel: +44 (0) 207 9930 035
Monday-Thursday, 9-5pm; Friday, 9-4pm (excluding UK bank holidays)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

This product is a medical device as defined in Directive 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5).

2.2 Label Elements

Signal word Not applicable

Hazard statements Not applicable

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

Precautionary statements Not applicable

2.3 Other hazards

For external use only. Avoid contact with eyes, mouth and broken or bleeding skin. Discontinue use if irritation develops. If irritation persists for more than 72 hours seek medical advice. Store in a cool dry place.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

| Declarable components | Conc. (%) | EC No. | CAS No. | Classification according to Regulation (EC) No. 1272/2008 | Specific concentration limits according to Regulation (EC) No 1272/2008 |
|-----------------------|-----------|-----------|------------|--|---|
| Dimethicone | ≤ 4.0 | | 63148-62-9 | Aquatic Chronic 4: H413 | - |
| Glycerin | ≤ 1.0 | 200-289-5 | 56-81-5 | Eye Irrit. 2: H319 | - |
| Benzalkonium chloride | ≤ 0.1 | 270-325-2 | 68424-85-1 | Acute Tox 4: H302, H312; Skin Corr 1B; H314; Aquatic Acute 1: H400 | - |

Although individual ingredients may be classified as hazardous, the levels contained in this mixture are not considered to be hazardous.

Paraffinum liquidum 6%
Other additives <6%
Water <75%

Full list of Hazard Statements are available in Section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

For industrial use of the liquid, if adverse effects (e.g. irritation of the airways) occur, remove patient from exposure and give fresh air and rest. If the patient continues to feel unwell, obtain medical attention.

Skin

For industrial use of the liquid, remove contaminated clothing and wash affected area with soap and water. If irritation occurs, seek medical attention. Launder contaminated clothing before re-use.

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

Eye

For industrial use of the liquid, in case of contact with eyes, irrigate with water, occasionally lifting eyelids. Seek prompt medical attention.

Ingestion

For industrial use of the liquid, if swallowed, wash out mouth thoroughly and give water to drink. Seek medical attention if significant amounts (e.g. more than a teaspoonful) are ingested, or for any symptoms occurring after ingestion. Do not induce vomiting, unless instructed by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

May cause eye irritation. Seek medical attention if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms as they occur.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Water spray, carbon dioxide, dry chemical and foam are compatible with the product. Remove containers from fire or cool them with water.

5.2 Special hazards arising from the substance or mixture

When heated sufficiently, product may decompose to form smoke and toxic fumes, gases or vapours.

5.3 Advice for firefighters

Fire fighters should wear an approved self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For industrial spills of the liquid, ensure full personal protection is worn (see Section 8). Keep unauthorised personnel from the spillage area.

6.2 Environmental precautions

Prevent leakage of product into water-courses or drainage system by diking with sand or other absorbent material. Contact authorities, water company, and waste-water treatment plant as appropriate if significant contamination occurs.

6.3 Methods and material for containment and cleaning up

Stop the source of leak or release. Clean up spill as soon as possible. Small spills can be mopped up with dry cloth. Collect larger spill using techniques such as sorbent

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

materials or pumping. Place material in suitable container for disposal in accordance with local and national regulations. Wash contaminated surfaces with water, and collect washings for safe disposal. Follow prescribed procedures for responding to large spills and reporting to appropriate authorities.

6.4 Reference to other sections

For recommended personal protective equipment see Section 8.
For disposal considerations see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For industrial use of the liquid, avoid contact with skin and eyes. Wear protective clothing as in Section 8. Good general ventilation is recommended.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well-ventilated place, away from direct sunlight. Do not allow to freeze. Keep container closed when not in use.

7.3 Specific end use

Identified in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters

EU Limit None

National Limit

| | Limit Value – Eight Hours | | Limit Value – Short term * | |
|----------------|---------------------------|-------|----------------------------|-------|
| Glycerol mist | | | | |
| Country | ppm | mg/m³ | ppm | mg/m³ |
| United Kingdom | | 10 | | |

* Short term is 15 minutes unless stated otherwise

8.2 Exposure controls

Engineering controls

For industrial use of the liquid, good general ventilation is recommended.

Personal protective equipment

Product is designed for skin use and is dermatologically tested.

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

For professional use of the liquid, the need for personal protective equipment should be based on a workplace risk assessment for the particular use. Prevent skin and eye contact by wearing chemical resistant gloves (e.g. rubber, neoprene, PVC) and safety goggles. Where more extensive contact may occur, wear suitable protective clothing (e.g. apron, sleeves, boots).

PPE should be to European (EN) standards. Consult manufacturers concerning breakthrough times.

Environmental exposure controls
Not available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|--|
| Physical state | Moist non-woven wipe |
| Colour | White wipe with a clear, colourless eluate |
| Odour | Slight green tea perfume |
| Melting/freezing point | ca. 0°C |
| Initial boiling point/range | ca. 100°C |
| Flammability | Not determined: water-based product |
| Lower and upper explosion limit | Not determined: water-based product |
| Flash point | Not determined: water-based product |
| Auto-ignition temperature | Not determined: water-based product |
| Decomposition temperature | Not determined: water-based product |
| pH | ca. 7 |
| Kinematic viscosity | Not determined: water-based product |
| Solubility | Soluble in water |
| Partition coefficient n-octanol/water | No data available |
| Vapour pressure | No data available |

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

Density and/or relative density Not determined: water-based product

Relative vapour density Not determined: water-based product

Particle characteristics Not applicable

9.2.1 Other information Not available

9.2.2 Other safety characteristics Not available

SECTION 10: Stability and reactivity

10.1 Reactivity

None known

10.2 Chemical stability

Stable under recommended storage and handling conditions.

10.3 Possibility of hazardous reactions

None known

10.4 Conditions to avoid

None

10.5 Incompatible materials

Oxidising agents. Contact with anionic substances will reduce effectiveness of the product.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Not classified as harmful by ingestion or skin contact. Inhalation may cause drowsiness or dizziness. Ingestion of liquid may cause intoxication.

Skin corrosion/irritation

Not likely to cause dermal irritation.

Serious eye damage/irritation

May cause eye irritation. Prolonged or repeat exposure may cause skin irritation.

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

Respiratory or skin sensitisation
Not likely to cause sensitisation.

Germ cell mutagenicity
No data available

Carcinogenicity
No data available

Reproductive toxicity
Not available

STOT-single exposure
No data available

STOT-repeated exposure
No data available

Aspiration hazards
Inhalation of vapours or liquid may cause drowsiness or dizziness.

11.2 Information on other hazard classes which relates to endocrine disrupting properties

Endocrine disrupting properties
Not available

Other information
Not applicable

SECTION 12: Ecological information

12.1 Toxicity

Contains substances (dimethicone and benzalkonium chloride) which can be toxic to aquatic organisms.

12.2 Persistence and degradability

No information available

12.3 Bioaccumulative potential

No information available

12.4 Mobility in soil

No information available

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

12.5 Results of PBT and vPvB assessment

No information available

12.6 Endocrine disrupting properties

No information available

12.7 Other adverse effects

No information available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

This product may be disposed of via the landfill, or by incineration. Disposal must be in accordance with current national and local regulations.

In industry, chemical residues generally count as special waste, and their disposal may be regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities or approved waste disposal companies who will advise you on how to dispose of special waste.

The wipes are not flushable or maceratable.

SECTION 14: Transport Information

Not classified for transport.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the mixture

Classification and Labelling of Substances and Preparation Dangerous for Supply. Workplace Exposure Limits EH40. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 with amendments.

15.2 Chemical safety assessment

Not available

SECTION 16: Other Information

Basis of classification

The mixture is self-classified on the basis of available information on the ingredients

List of hazard statements

SAFETY DATA SHEET

Contiplan by Clinell

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 8th June 2023

Version Number: 5

H302: harmful if swallowed
H312: harmful in contact with skin
H314: causes severe skin burns and eye damage
H319: causes serious eye irritation
H400: very toxic to aquatic life
H413: May cause long lasting harmful effects to aquatic life

This safety data sheet was compiled using the ECHA Guidance on the compilation of Safety Data Sheets, Version 4.0, December 2020.

Disclaimer: This information is furnished without warranty express or implied, except that it is accurate to the best of our knowledge.

It relates to the specific material designated herein, and does not relate to the use in combination with any other material or in any process. We assume no legal responsibility for use or reliance upon this information.